K011601

ARDO

JUN - 8 2001

Ardo Suction Pumps
master, senator

510 (k) Summary

1. **Submitted by:**
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2. **Contact Person:**
   Eva Krähenbühl, Marketing Manager

3. **Date Prepared:**
   18 April 2001

4. **Product Classification:**
   - Device Name: Ardo Suction Pumps master, senator
   - Common Name: Suction Pump
   - Classification Name: Powered Suction Pump (per 21 CFR 878.4780)

5. **Predicate Devices:**
   - egnell compact suction pump by Ameda AG, K853917, November 25, 1985
   - Dominant suction pump by Medela AG, K983552, January 7, 1999

6. **Device Description:**
   The Ardo Suction Pumps master and senator are high performance suction pumps with maintenance-free glass piston/cylinder technology and a modern, functional design. They are the successor models of the egnell compact suction pump operating on the same basic principles.

   The mechanical over-flow safety device in the lid jar and the bacterial filter protect the pump against contamination. The suction pump is connected to the collection jars by means of collapse-resistant suction tubing. A longer piece of patient tubing is also connected to the jar. The latter transports the fluids from the patient to the jar. However, the tubing does not contact the patients directly. When the suction pump is switched to the ON position, the circuits direct electrical current from the external AC power supply to the pump/motor assembly. The pump operates to evacuate air from the collection jar. The resulting subatmospheric condition causes air to flow upward from the patient suction tubing and into the jars. Vacuum can be set by turning the adjustment knob.

   The difference between the master and senator is the suction capacity (master: 45 liter/minute, senator: 30 liter/minute). All other features are substantially equivalent.

7. Indications for Use:

The Ardo Suction Pumps master and senator are indicated for vacuum extraction, aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials from wounds or from a patient's airway or respiratory support system, either during surgery or at the patient's bedside.

The indications for use for Ardo Suction Pumps master and senator are identical to the predicate device, Dominant, K983552.

8. Test:

The following standards were used in testing the suction pumps:

- ISO 10079-1: Medical Suction Equipment – Part 1: Electrically powered suction equipment
- ISO 10079-3: Medical Suction Equipment – Part 1: Suction equipment powered from a vacuum or pressure source
- IEC 601-1: Medical Electrical Equipment – Part 1: General requirements for safety

9. Conclusion:

It is concluded that the proposed Ardo Suction Pumps master and senator are safe and effective for their intended use and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2001

Ardo Medical Ag
c/o Mr. Mark Job
TÜV Product Service, Inc.
1775 Old Highway 8
New Brighton, Minnesota 55112

Re: K011601
Trade/Device Name: Ardo Suction Pumps Master, Senator
Regulation Number: 878.4780
Regulatory Class: II
Product Code: BTA
Dated: May 15, 2001
Received: May 24, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011601

Device Name: Ardo Suction Pumps master, senator

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011601

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR § 801.109)